Exhibit E

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Did You Join Us for the Webinar Nitrosamines: A Moving Target? Here's Your Recap!

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Webinar | Regulatory Affairs | Guide

Our recent webinar, Nitrosamines: A Moving Target was a deep-dive into the issue of Nitrosamines impurities and how you can stay on top of the various evaluation requirements to remain compliant.

During the webinar, Diana Van Geenhoven, our head of global compliance, Lena Ben Moha-Lerman, Senior Director of Lifecycle Management within Teva api's R&D team and **Vesna Prgomet,** our Director Global Regulatory Affairs, spoke to our listeners about the critical three-step approach when it comes to Nitrosamines, Risk Assessment, Confirmatory Testing and Changes for Marketing Authorization.

If you missed the live event, here are your highlights!

Access webinar recording

What changes should I look out for when it comes to Nitrosamines?

Over the past three years, there have been a lot of changes in Nitrosamines regulations. While the evaluation requirements started out with a focus on NDMA, now the guidelines contain many other Nitrosamines, too. It started out with Valsartan as the main product to be included, and now all chemical synthesized medicinal products as well as products produced by fermentation and biological syntheses have to be assessed. Acceptable Intake levels also have been changed during the last years.

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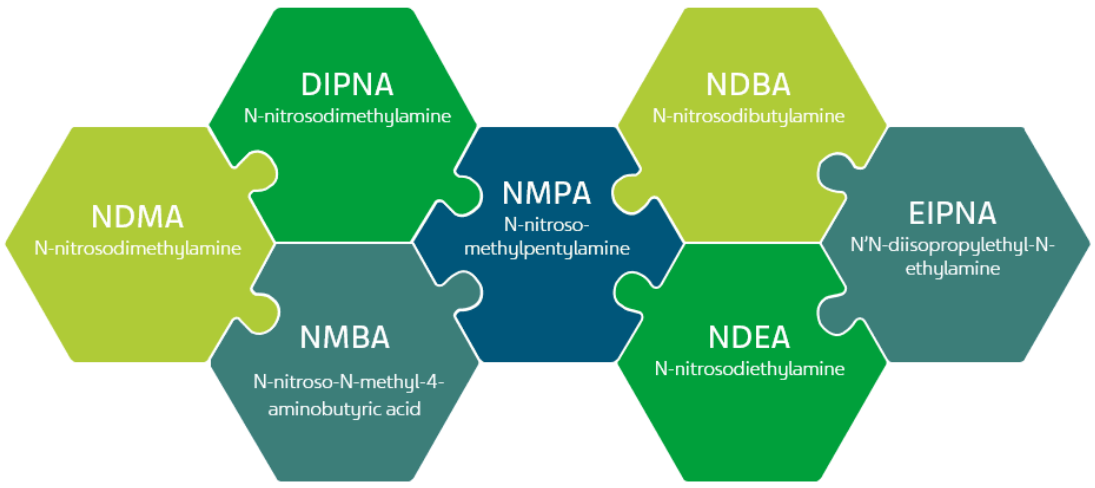
Got It



Other extensions to the regulations include regarding the root causes for the presence of Nitrsosamines for example checking for cross-contamination as part of your evaluation.

In some cases, the evaluation criteria actually has become less stringent. For example, back in 2019 the FDA said that Nitrosamines in Sartans should be undetectable. However, in 2020 – the FDA updated this with new guidance and relaxed this requirement. Timelines have also been changed, especially in response to the COVID-19 pandemic. For example, the EMA relaxed the deadline for the first step in the Nitrosamines assessment from March 2020 to September 2020 and then again to March 2021.

Lastly, several publications have been issued over the past three years which explain the different ways that you can test for Nitrosamines, depending on the product you're testing.

Risk mapping for Nitrosamines

There are three steps for Nitrosamines' risk mapping. The first is the theoretical risk assessment. If a risk is found, you then move to confirmatory testing. If indeed Nitrosamines have been found at a higher amount than the limit, you will need to optimize or change the process before submitting this change to the relevant regulatory agencies. Let's look at each stage in more detail.

Risk assessment

Theoretical assessment should address all root causes as defined by relevant guidelines and can be grouped in three potential sources for risk with Nitrosamines. These are **the chemical process, cross-contamination and contaminated raw materials/solvents.**

Nitrosamines formation is attributed to a reaction between the secondary amine and nitrite ion, therefore Nitrosamines can be formed in chemical process only if both of these are present. If one of those components is missing there will be no risk of Nitrosamines formation.

It is important to emphasize that secondary amine doesn't have to be present as it is, it could also be sourced from primary/tertiary/quaternary amine that is used in the process. Secondary amines can be also process intermediates of the API itself. Similarly, nitrite can be used itself in the process or it could come from other sources such as hydroxylamine or nitric acid. Process water should also be assessed for the presence of nitrite ions, as they can react with amines used in the process.

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***Remember**: Secondary amine and nitrite ion don't have to be used in the same synthetic step. Traces of reagents might be carried over to the later steps.*

Another aspect of potential risk could be contaminated starting materials and solvents, such as recycled solvents or materials that we source from a third-party. To address this risk at Teva api, we send dedicated questionnaires to all our vendors and based on their answers we conclude whether or not there is a potential risk. In case we conclude that there is a risk – API produced from this vendor is subjected to confirmatory analysis.

Confirmatory testing

Confirmatory testing is required for commercial products as well as for any new products to be launched. Different regulators have varying amounts of Nitrosamines that are considered to be acceptable. For example, under the EMA guidelines, less than 10% of the Acceptable Intake is considered to be low enough risk, while the FDA doesn't spell out this ratio. The EMA also says that 10% of commercial batches should be tested, while the FDA does not have guidance on the number of batches to be tested.

At Teva api, we develop and validate highly sensitive analytical methods for confirmatory testing, utilizing machines such as GC-MS 3Q or LC-MS 3Q.

Our methods are developed to monitor specific Nitrosamines which according to the process in question could potentially be present in each API in line with all the current regulations and best-practices.

Submitting a change

Once the risk assessment activities have been completed, you'll have a clear idea of what changes need to be implemented. For example, you may need to change the manufacturing process by adding an extra purification stage, adjusting a process, or adding a new step. You may also need to make changes to the premises or the equipment you use.

You'll need to validate the specification and method you've developed to fix the problem, and ensure that you've controlled the change going forward, for example changing a supplier or codifying the new manufacturing process.

Now, it's time to communicate the changes to the customers, MAH, authorities and to regulatory boards. At Teva api, as an API manufacturer and a CEP holder – we submit these change requests to EDQM, noting whether this is a minor or a major change in process. For example, the inclusion of mutagenic impurity in API specification is a minor revision, and so is any update in the impurity section.

***Remember**: In relevant case when nitrosoamines risk assessment needs to be added, even if the risk assessment only concludes that there is no risk being added – EDQM still requires this to be submitted as a minor revision (not as notification).*

Facts and dates for your diary

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- For US market, DMF amendment include relevant updates should be prepared and submitted to FDA in collaboration with MAH. FDA allows proposed process to be submitted with estimate for removal of the original process. The different synthetic processes should be identified by separate codes.
- Deadline for MAHs to submit changes to FDA is **Oct 1st 2023.**
- If the original process cannot be discontinued within a reasonable timeframe, the new or revised process should be submitted in a separate DMF.

At Teva api, we work together with our vendors, customers and partners to ensure that we carry out a thorough risk assessment and testing process, ensuring that we have plenty of time to communicate and submit changes before the dates provided.

If you'd like any more information on how we work to control Nitrosamines in our API manufacturing, reach out here, or ***watch the complete webinar****.*

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